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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,369	08/27/2003	Andrew A. Potter	9000-0057.01	7295

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,369	POTTER ET AL.	
	Examin r	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on th cov r sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 9-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2,3 and 9-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 3, 9, 46-56, and 68-75 drawn to multiple epitope fusion polypeptides of Streptococcus GapC proteins, or molecules or compositions comprising such fusion polypeptides, classified in class 424, subclass 203.1,

II. Claims 10-36, drawn to polynucleotides encoding for multiple epitope fusion proteins, and a method of producing said proteins through recombinant cell expression classified in class 536, subclass 23.4,

III Claims 37-45, methods of producing said polypeptides through recombinant cell expression classified in class 536, subclass 23.4,

IV. Claims 57-59, drawn to methods of treating or preventing bacterial infections by administering polypeptide compositions to a vertebrate subject, classified in class 424, subclass 185.1,

V. Claims 60-62, drawn to methods of treating or preventing bacterial infections by administering polynucleotide compositions to a vertebrate subject, classified in class 514, subclass 44,

VI. Claims 63-65, drawn to antibodies to multiple epitope fusion proteins classified in class 424, subclass 150.1,

VII Claims 66 and 67, drawn to a method of detecting Streptococcus antibodies in a biological sample by reacting said sample with a multiple fusion polypeptide, classified in class 435, subclass 7.1.

For each of Inventions I to VII above, restriction to one of the following is also required under 35 U.S.C. 121. . Therefore, election is required of one of Groups I – VII, and must elect a particular combination of epitopes to be examined. I.e., the Applicant may elect subinvention (F) the polypeptide of SEQ ID NO: 22 (or for those inventions dealing with polynucleotides, the polynucleotide of SEQ ID NO: 21), or the Applicant may elect a combination of epitopes each identified by a combination of an election of one of (A)-(E) and of one of (1)-(5). Thus, the Applicant must elect one of Groups I-VII, and either subinvention (F), or another combination of epitopes: each selected from one of (A)-(E) as follows:

(A). the polynucleotide of SEQ ID No: 11 or the polypeptide of SEQ ID No: 12 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 1),

(B) the polynucleotide of SEQ ID No: 13 or the polypeptide of SEQ ID No: 14 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 2),

(C) the polynucleotide of SEQ ID No: 15 or the polypeptide of SEQ ID No: 16 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 3),

(D) the polynucleotide of SEQ ID No: 17 or the polypeptide of SEQ ID No: 18 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 4),

(E) the polynucleotide of SEQ ID No: 19 or the polypeptide of SEQ ID No: 20 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 5),

(F) the polynucleotide of SEQ ID NO: 21 or the polypeptide of SEQ ID NO: 22 (corresponding respectively to the polynucleotide and the polypeptide of Fig. 6);

and one of the (1)-(5) as follows:

(1) the amino acid sequence at about amino acid positions 61-81 or a sequence encoding that sequence

(2) the amino acid sequence at about amino acid positions 102-112 or a sequence encoding that sequence

(3) the amino acid sequence at about amino acid positions 165-172 or a sequence encoding that sequence

(4) the amino acid sequence at about amino acid positions 248-271 or a sequence encoding that sequence

(5) the amino acid sequence at about amino acid positions 286-305. or a sequence encoding that sequence

The inventions are distinct, each from the others, for the following reasons:

2. Inventions (1) to (5) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the inventions (1)-(5) has a separate utility as an immunogenic fragment usable in the described multiple epitope fusion polypeptide. Each may used be independently of, or together with, the other fragments. Because the fragments are separately usable, they are distinct from each other.

3. Inventions (A)-(F) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the inventions (A)-(E) has a separate utility as an immunogenic sequence usable in the described multiple epitope fusion polypeptide. Each may be used independently of, or together with, the other sequences. Because the sequences are separately usable, they are distinct from each other.

4. Inventions II and either of Groups III or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, inventions relate to polynucleotides products, methods of using those molecules for the production of polypeptides, and to methods of using those products to treat bacterial infections. The polynucleotides are usable in other processes, such a producing polypeptides, or in cell transformation (App., p. 32), or in hybridization assays. Inventions II and III and V are therefore distinct because the product may be used in materially different processes.

5. Invention II, III, and V; and inventions I, IV, and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to polynucleotides, methods of using

polynucleotides; and to proteins (including proteins encoded by the polynucleotides) and methods of using proteins. The polynucleotides inventions are distinct from the polypeptide inventions because they are not disclosed as usable together, and because the two types of molecules have different modes of operation. For example, in treatment of bacterial diseases, proteins can act directly, either by inducing the creation of antibodies, or by being antibodies to the source of the infection themselves. However, a polynucleotide must act indirectly, by being transcribed to produce a protein, which may act directly, in order to treat an infection.

Although the polypeptides of invention I have a product/ process of making relationship with the polynucleotide method of use of invention II, the two inventions are still distinct. Inventions in this relationship are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Since the polypeptides may also be produced by purification, they are distinct from the method of producing them in invention VI.

6. Inventions I; and IV and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case invention I is to a multiple epitope fusion polypeptide, and inventions III and VI are to two materially different methods of using the polypeptide- the first to treat a bacterial infection, the second to detect antibodies in an assay Since invention I is usable

in at least two separate processes, it is distinct from the processes of using in inventions III and VI.

7. Inventions I, IV and VII, and invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. The inventions of Groups I, III, and VI relate to multiple epitope fusion proteins and methods of using them. Invention V relates to antibodies to the protein. The antibodies are not disclosed as usable with the proteins, and perform different functions than them. Although the proteins are usable to detect the antibodies, that is not a use of the antibodies, thus is not a disclosure of using the antibodies and proteins together. The protein's function is to induce the development of antibodies to prevent or reduce a bacterial infection, while the antibodies are intended to directly fight off bacterial infections. Thus, the two inventions are distinct.

Conclusion

8. Because these inventions are distinct for the reason given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

9. Applicant is advised that in order for the reply to this requirement to be complete, it must include an election of an invention to be examined as described above, even if the requirement is traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner

JAMES HOUSEL 2/9/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600